FDA News

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FDA Announces Series of Changes to the Class of Marketed Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

The Food and Drug Administration (FDA) today announced a series of important changes pertaining to the marketing of the non-steroidal anti-inflammatory class of drugs, including COX-2 selective and prescription and non-prescription (over-the-counter (OTC)) non-selective NSAID medications. A list of these products is available on the Internet at http://www.fda.gov/cder/drug/infopage/cox2/default.htm.

"Today's actions protect and advance the health of the millions of Americans who rely on these drugs everyday," said Dr. Steven K. Galson, Acting Director of FDA's Center for Drug Evaluation and Research (CDER). "FDA is providing the public information based on the latest available scientific data to guide the careful and appropriate use of these drugs aimed at maximizing their potential benefits and minimizing their risks."

FDA has asked Pfizer, Inc. to withdraw Bextra (valdexocib) from the market because the overall risk versus benefit profile for the drug is unfavorable. FDA has also asked Pfizer to include a boxed warning in the Celebrex (celecoxib) label. Pfizer has agreed to suspend sales and marketing of Bextra in the U.S., pending further discussions with the agency. Pfizer has agreed to work with FDA on the boxed warning for Celebrex. FDA is asking manufacturers of all other prescription NSAIDs to revise their labels to include the same boxed warning highlighting the potential for increased risk of cardiovascular (CV) events and gastrointestinal (GI) bleeding associated with their use. Manufacturers of Celebrex and all other prescription NSAIDs will be asked to revise their labeling to include a Medication Guide for patients to help make them aware of the potential for CV and GI adverse events associated with the use of this class of drugs.

In addition, FDA is asking the manufacturers of all OTC NSAIDs to revise their labels to include more specific information about the potential CV and GI risks, and information to assist consumers in the safe use of the drugs. FDA is also asking manufacturers of OTC NSAIDs to include a warning about potential skin reactions. The labeling of the prescription NSAIDs already addresses potential skin reactions.

This current reexamination of the CV risks of NSAIDs began after Merck conducted a voluntary worldwide withdrawal of its COX-2 selective NSAID, Vioxx (rofecoxib), in September 2004. FDA will carefully review any proposal from Merck for resumption of marketing of Vioxx.

These actions are based on the available scientific data, including data accumulated since the drugs were approved. The FDA has carefully considered the presentations, discussions, and recommendations from the joint meeting of the Agency's Arthritis and Drug Safety and Risk Management Advisory Committee held on February 16-18, 2005.

To inform the public and healthcare community of its decisions, FDA today issued a Public Health Advisory (PHA) and updated patient and healthcare practitioner fact sheets.

Additional information about today's announcements is available on FDA's Web site at www.fda.gov/cder. Information can also be obtained by calling 1-888-INFO-FDA (888-463-6332).

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COX-2 Main Page
Questions and Answers
Public Health Advisory

COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

The Food and Drug Administration (FDA) has asked Pfizer to voluntarily remove Bextra (valdecoxib) from the market. FDA is also asking manufacturers of all marketed **prescription** Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use.

Manufacturers of **non-prescription** (over-the-counter) NSAIDs are also being asked to revise their labeling to provide more specific information about the potential CV and GI risks of their individual products and remind patients that these products of the limited dose and duration of treatment in accordance with the package instructions.

In making these decisions, the Center for Drug Evaluation and Research (CDER) considered the risk/benefit profile for each of the drugs. Also considered was;

- review of the regulatory histories and new drug application (NDA) databases of the various NSAIDs,
- FDA and sponsor background documents prepared for the joint Advisory Committee meeting of FDA's Arthritis and Drug Safety and Risk Management Advisory Committees, held February 16-18, 2005,
- all materials and data submitted by other stakeholders to the Advisory Committee meeting, presentations made at the joint meeting
- the specific votes and recommendations made by the joint Committee.

Further information regarding the decisions being announced and specific details regarding the individual products can be found within the documents posted to this Web page.

- Public Health Advisory
- FDA Press Release
- Questions and Answers

- COX-2 Selective Drugs
- COX-2 Selective Non-steroidal Anti-inflammatory Drugs (NSAIDs) and Prescription and Over-the-Counter (OTC) Non-selective NSAIDs Approved Under New Drug Application (NDA) Abbreviated New Drug Application (ANDA) Table of Drug Products

COX-2 Selective Drugs

Bextra (valdecoxib)

Current Information

- Healthcare Professional Sheet [PDF] [HTML]

Background Information

- FDA Talk Paper (12/9/2004)
- Questions and Answers: Strengthening Warnings on Bextra (12/9/2004)
- Consumer Information Sheet
- FDA Issues Public Health Advisory Recommending Limited Use of Cox-2 Inhibitors. FDA Talk Paper (12/23/2004)
- Public Health Advisory: Non-Steroidal Anti-Inflammatory Drug Products (NSAIDs) (12/23/2004)

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Celebrex (celecoxib)

Current Information

- Patient Information Sheet [PDF] or [HTML]
- Healthcare Professional Information
    - Healthcare Professional Sheet [PDF] or [HTML]
    - Prescribing Information (Celebrex Label)

Background Information

FDA Alert: 3/2005. Based on emerging information, including preliminary reports from one of several long term National Institutes of Health (NIH) prevention studies, the risk of cardiovascular events (composite endpoint including MI, CVA and death) may be increased in patients receiving Celebrex. FDA will be analyzing all available information from these studies to determine whether additional regulatory action is needed.

- Regulatory History of Celebrex from Drugs@FDA

- FDA Statement on the Halting of a Clinical Trial of the Cox-2 Inhibitor Celebrex (12/17/2004)
- FDA Issues Public Health Advisory Recommending Limited Use of Cox-2 Inhibitors. FDA Talk Paper (12/23/2004)
- Public Health Advisory: Non-Steroidal Anti-Inflammatory Drug Products (NSAIDS) (12/23/2004)

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Vioxx (rofecoxib)

Background Information

Merck & Co., Inc. announced a voluntary withdrawal of Vioxx (rofecoxib) from the U.S. and worldwide market due to safety concerns of an increased risk of cardiovascular events (including heart attack and stroke) in patients on Vioxx. Vioxx is a prescription COX-2 selective, non-steroidal anti-inflammatory drug (NSAID) that was approved by FDA in May 1999 for the relief of the signs and symptoms of osteoarthritis, for the management of acute pain in adults, and for the treatment of menstrual symptoms. Vioxx was later approved for the relief of the signs and symptoms of rheumatoid arthritis in adults and children.

- Statement by Dr. Steven Galson, Acting Director, Center for Drug Evaluation and Research (CDER), Regarding November 18, 2004, Committee on Finance of the U.S. Senate Hearing on Drug Safety and the Worldwide Withdrawal by Merck & Co., Inc., of Vioxx. FDA Statement (11/18/2004)
- Congressional Statement on Vioxx and Drug Safety (Posted 11/18/2004)
- FDA releases a statement on Vioxx and recent allegations, and on the Agency's continued commitment to sound science and peer review. FDA Statement (Posted 11/17/2004)
- Slide Presentation by Sandra Kweder, M.D., November 10, 2004. [HTML] [PowerPoint] (Posted 11/10/2004)
- FDA Acts to Strengthen the Safety Program for Marketed Drugs. FDA Statement (11/5/2004)
- 9/30/2004 Study Report (Posted 11/2/2004)
- FDA Issues Public Health Advisory on Vioxx as its Manufacturer Voluntarily Withdraws the Product. FDA News (9/30/2004)
- FDA Public Health Advisory: Safety of Vioxx (9/30/2004)
- Vioxx (rofecoxib) Questions and Answers (9/30/2004)

Other Prescription Non-selective NSAIDs

Current Information

- Patient Information Sheet (coming soon)
- Healthcare Professional Information [PDF] [HTML]

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COX-2 Selective Non-steroidal Anti-inflammatory Drugs (NSAIDs) and Prescription and Over-the-Counter (OTC) Non-selective NSAIDs Approved Under New Drug Application (NDA) Abbreviated New Drug Application (ANDA)

COX-2 Selective NSAIDs	
Chemical Name	**Brand Name**
Celecoxib	Celebrex
Valdecoxib	Bextra
Rofecoxib	Vioxx

Non-selective NSAIDs	
Chemical Name	**Brand Name**
Diclofenac	Cataflam, Voltaren, Arthrotec (combination with misoprostol)
Diflunisal	Dolobid
Etodolac	Lodine, Lodine XL
Fenoprofen	Nalfon, Nalfon 200
Flurbiprofen	Ansaid
Ibuprofen**	Motrin, Motrin IB, Motrin Migraine Pain, Advil, Advil Migraine Liqui-gels, Ibu-Tab 200, Medipren, Cap-Profen, Tab-Profen, Profen, Ibuprohm, Children's Elixsure *, Vicoprofen (combination with hydrocodone), Combunox (combination with oxycodone)
Indomethacin	Indocin, Indocin SR, Indo-Lemmon, Indomethegan
Ketoprofen**	Oruvail, Orudis, Actron
Ketorolac	Toradol
Mefenamic Acid	Ponstel
Meloxicam	Mobic

Nabumetone	Relafen
Naproxen**	Aleve, Naprosyn, Anaprox, Anaprox DS, EC-Naproxyn, Naprelan, Naprapac (copackaged with lansoprazole)
Oxaprozin	Daypro
Piroxicam	Feldene
Salsalate	Disalcid
Sulindac	Clinoril
Tolmetin	Tolectin, Tolectin DS, Tolectin 600

*There are many OTC Combinations with ibuprofen: Advil Cold And Sinus, Advil Cold, Advil Allergy Sinus, Children's Advil Allergy Sinus, Ibuprohm Cold and Sinus, Sine-Aid IB, Children's Motrin Cold.

**There are over-the-counter versions of these prescription medications.

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